Serial No: 10/612,379 .

Amendment dated.June 24, 2005

Reply to Office Action of May 24, 2005

## **REMARKS**

Claims 1-39 are currently pending in this application. Claims 1-3, 5, 7 and 9 have been allowed and claims 11-39 have been withdrawn from consideration. By this amendment, claim 4 has been amended and new claim 40 has been added. No new matter has been entered by these amendments. Examiner Gamett's comments in the March 24, 2005 Office Action have been carefully considered and reconsideration of this application in view of the current amendments and following remarks is respectfully requested.

## Rejection Under § 112, First Paragraph

Claims 4, 6, 8 and 10 have been rejected as not enabled by the specification under 35 U.S.C. § 112, first paragraph. Specifically, the Examiner stated that while the specification is enabling for a nucleic acid having the sequence of SEQ ID NO: 1 and the rh133 and n2400 mutant alleles thereof, recombinant vectors, cells and methods of making the encoded protein, "the specification does not reasonably provide enablement for the mutant nucleic acids, proteins, vectors, cells and methods of claims 4, 6, 8, and 10" (3/24/05 Office Action, p. 5). According to the Examiner:

All claims are dependent from claim 4, [the claim language of which]...permits a limitless number of variants. The specification, however, teaches only three mutants, designated rh133, n561 and n2400. The only disclosed assay for activity of the claimed nucleic acid is rescue of embryos with an exc-4 null mutant phenotype. Thus, isolation and characterization of each new variant would require extensive experimentation. Due to the large quantity of experimentation necessary to isolate and characterize mutants, the lack of direction/guidance presented in the specification regarding mutants..., the absence of working examples..., the state of the prior art which established the unpredictability of the phenotype of variants, and the breadth of the claims which fail to recite functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

(3/24/05 Office Action, pp. 5-6).

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Applicant respectfully traverses this rejection and submits that the current the specification enables a skilled artisan to make the mutant nucleic acids, proteins, vectors, and cells of claims 4, 6, 8 and 10 without undue experimentation. Applicant specifically points to paragraphs 36- 43 at pages 10-17 of the application which, in view of the state of the art at the time applicant's invention was made, provide more than adequate disclosure for a skilled artisan to make the claimed nucleic acids (para. 36-37), vectors (para. 38-40), cells (para. 41), and proteins (para. 43).

Notwithstanding applicant's traversal, in order to expedite issuance of this application, applicant has amended claim 4 to clarify that the isolated nucleic acid encodes for a mutant chloride intracellular channel protein. In view of this amendment, the language of claims 4, 6, 8 and 10 specifically provides nucleic acid variants that encode for mutant chloride intracellular channel protein, rather than "a limitless number of variants" as alleged by the examiner (3/24/05 Office Action, p. 5). Importantly, in view of this amendment, isolation and characterization of the claimed variants can be accomplished by a skilled artisan without extensive or undue experimentation.

In view of the foregoing, applicant respectfully requests the withdrawal of the rejections of claims 4, 6, 8 and 10 under 35 U.S.C § 112, first paragraph.

## Rejection Under 35 U.S.C. § 102(b)

Claims 4 and 6 were rejected under 35 U.S.C. § 102(b) as anticipated by Sulston, Accession No. AL 132876.4 ("Sulston") which the Examiner alleges discloses a *C. elegans* YAC clone comprising 100% identity to SEQ ID NO: 1 of this application. The examiner stated that the "sequence disclosed by Sulston thus is 'an isolated nucleic acid that has a sequence identical to the sequence of SEQ ID NO: 1, except for the presence of one or more ... deletions' as recited in claim 4, (sic) in a recombinant vector, as in claim 6." (3/24/05 Office Action, p. 6).

In response, as discussed above, applicant has amended claim 4 to clarify that the isolated nucleic acid encodes for a mutant chloride intracellular channel protein. Applicant respectfully submits that this amendment renders moot the 35 U.S.C. § 102(b) rejection of

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claims 4 and 6 because Sulston does not teach an isolated nucleic acid that encodes for a mutant chloride intracellular channel protein. Because Sulston does not teach every aspect of applicant's claimed invention, applicant respectfully submits that the present invention is patentable and not anticipated by Sulston and respectfully requests withdrawal of the rejections of claims 4 and 6 under 35 U.S.C. § 102(b).

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## **CONCLUSION**

In view of the foregoing amendments and remarks, applicant believes that he has fully responded to the Examiner's concerns and that each of the pending claims is in condition for immediate allowance. Accordingly, applicant respectfully requests consideration and immediate allowance of all the claims.

Applicant requests that any questions concerning this matter be directed to the undersigned at (973) 775-8919.

No fee is deemed necessary for filing this Amendment. However, the Commissioner is hereby authorized to charge any fees that may be required to the undersigned attorney's Deposit Account No. 02-4270.

June 24, 2005

Date

Respectfully submitted,

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